

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

ARAMIC LLC, et al.,  
Plaintiffs,

v.

REVANCE THERAPEUTICS, INC., et al.,  
Defendants.

Case No. 21-cv-09585-AMO

**ORDER GRANTING DEFENDANTS’  
MOTION TO STRIKE AND MOTION  
TO DISMISS**

Re: Dkt. Nos. 91, 92

This is a securities fraud case about the U.S. Food and Drug Administration’s review of a drug developed by Revance Therapeutics, Inc. (“Revance”). Before the Court are Defendants’ motion to strike a declaration attached as an exhibit to Plaintiffs’ second amended complaint (“SAC”) and Defendants’ motion to dismiss Plaintiffs’ SAC. The matters are fully briefed and suitable for decision without oral argument. *See* Civil L.R. 7-6. Having read the papers filed by the parties and carefully considered their arguments and the relevant legal authority, the Court hereby **GRANTS** both motions for the following reasons.

**I. BACKGROUND**

Plaintiffs Aramic LLC and Tang Family Investor Group (collectively, “Lead Plaintiffs”) are stockholders of Defendant Revance Therapeutics, Inc., a biotechnology company that develops and sells skin treatment drugs.<sup>1</sup> SAC ¶ 2. Revance sought U.S. Food and Drug Administration (“FDA”) approval for DaxibotulinumtoxinA (“DAXI”), an injectable drug used to smooth frown

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<sup>1</sup> As it must, the Court accepts Plaintiffs’ allegations in the SAC as true and construes the pleadings in the light most favorable to them. *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008) (citation omitted).

lines. SAC ¶¶ 2, 4. Plaintiffs seek to represent purchasers of Revance stock between August 5, 2021 and October 15, 2021 (the “class period”).<sup>2</sup> SAC ¶ 1.

Drug developers like Revance that seek FDA approval must submit to the FDA a Biologics License Application (“BLA”). SAC ¶ 4. Review of the BLA typically involves inspection of the drug manufacturing facility by the FDA to evaluate company compliance with Current Good Manufacturing Practices (“cGMP”) regulations, assess readiness for commercial manufacturing, ensure conformance to the submitted application, and ensure the integrity of data submitted with the BLA. SAC ¶ 4. Following an inspection, the FDA may then issue a Form 483 with observations of potential non-compliance with cGMP regulations. SAC ¶ 10. The company then has fifteen days to respond. SAC ¶ 89. If the FDA does not approve a BLA, it issues a Complete Response Letter (“CRL”) explaining why the FDA did not approve the drug. SAC ¶ 21.

After years of developing DAXI, Revance announced its submission of a BLA for the drug on November 25, 2019, and stated that it anticipated potential FDA product approval at the end of 2020. SAC ¶¶ 6, 60. After delays due to COVID-19, the FDA’s pre-approval inspection of the manufacturing facility was completed on July 2, 2021. SAC ¶ 7. The FDA subsequently issued Revance a Form 483, which contained five “inspectional observations.” SAC ¶ 10. The first two observations focused on the deterioration of Revance’s working cell banks (“WCBs”) (cell tissues extracted from a repository to produce drug substance and product) and Revance’s new WCB not being fully qualified and being a different manufacturing process than proposed in the BLA. SAC ¶¶ 74-87. The remaining three observations concerned lack of oversight of outsourced activities for the quality control unit, lack of indicators of process performance, and lack of a “quality agreement” in place with a third-party facility. SAC ¶ 88.

Revance provided a written response to the Form 483 in July 2021. SAC ¶ 90. The response explained that it had enough drug substance from a qualified WCB to support commercial production of DAXI. SAC, Ex. C (Form 483 Response) at 10. Revance also explained that it planned to qualify the new WCB, and believed that qualification was a “post

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<sup>2</sup> Plaintiffs previously sought to represent individuals who purchased stock between November 25, 2019 and October 15, 2021. ECF 58 at 6.

1 approval activity.” *Id.* To that end, Revance stated that it “fully understands that the current WCB  
2 aged and our new WCB will not be fully qualified at the licensure. However, we have a fully  
3 functional [redacted] that can last for more than [redacted] as well as [drug substance] inventory to  
4 support [drug product] production through [redacted]. Given that supply shortage is not a  
5 concern, Revance proposes to submit a post approval application for the WCB qualification  
6 package per approved protocol once available. . . [.]” *Id.* at 10-11. Additionally, Revance  
7 disagreed with the FDA’s observation that it was using a different manufacturing process than that  
8 proposed for licensure. *Id.* at 7.

9 To address the remaining observations, Revance executed a quality agreement with a third-  
10 party facility on July 16, 2021, adjusted the way it calculated percentage yield, and amended its  
11 record-keeping details and photo clarity. SAC, Ex. C at 12-14, 17-18. On August 5, 2021,  
12 Revance issued a press release stating that the FDA initiated its pre-approval inspection in June  
13 and that Revance anticipated approval of DAXI in 2021. SAC ¶ 103. On October 15, 2021, the  
14 FDA issued a CRL denying Revance’s BLA for DAXI. SAC ¶ 115. On March 8, 2022, Revance  
15 resubmitted its BLA. SAC ¶ 122. In September 2022, following the issuance of another Form  
16 483 in July 2022, the FDA approved DAXI. SAC ¶¶ 125-126.

17 Plaintiffs filed this securities class action on December 10, 2021, against Defendants Mark  
18 Foley, Tobin Schilke, and Abhay Joshi (“Individual Defendants”) and Revance (collectively,  
19 “Defendants”). ECF 1. Plaintiffs filed their first amended complaint on November 7, 2022, which  
20 the Court dismissed with leave to amend on April 2, 2024. ECF 86. On May 2, 2024, Plaintiffs  
21 filed the operative SAC, alleging that certain statements Defendants made during the class period  
22 regarding the timing and likelihood of FDA approval of DAXI were false or misleading in  
23 violation of Sections 10(b) and 20(a) of the Securities Exchange Act (“Exchange Act”). SAC  
24 ¶¶ 217-32. On May 28, 2024, Defendants filed a motion to dismiss the SAC under Federal Rule  
25 of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, ECF 92,  
26 as well as a motion to strike the declaration of Suzanne Sensabaugh that Plaintiffs attached to the  
27 SAC, ECF 91.

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## II. LEGAL STANDARD

A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a). Federal Rule of Civil Procedure 12(b)(6) allows a defendant to move to dismiss a complaint for failing to state a claim upon which relief can be granted. “Dismissal under Rule 12(b)(6) is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory.” *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). To survive a Rule 12(b)(6) motion, a plaintiff must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when a plaintiff pleads “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing the plausibility of a complaint, courts “accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party.” *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Nonetheless, courts do not “accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences.” *In re Gilead Scis. Secs. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008).

Plaintiffs in securities fraud cases must satisfy both the pleading requirements of Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (“PSLRA”). *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Rule 9(b) requires that claims alleging fraud must “state with particularity the circumstances constituting fraud . . . .” Fed. R. Civ. P. 9(b). The PSLRA mandates that “the complaint shall specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading.” 15 U.S.C. § 78u-4(b)(1)(B). The PSLRA further requires that the complaint “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314 (2007) (quoting 15 U.S.C. § 78u-4(b)(2)(A)). A plaintiff must thus allege that “the defendant[] made false or misleading statements either intentionally or with deliberate recklessness.” *In re VeriFone Holdings*, 704 F.3d at 701 (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)).

### III. DISCUSSION

#### A. Request for Judicial Notice

Courts are typically limited to the contents of the complaint when considering a motion to dismiss but may take judicial notice of facts that are “not subject to reasonable dispute.” Fed. R. Evid. 201(b). Courts may consider documents incorporated into the complaint by reference, *Tellabs*, 551 U.S. at 322, and take judicial notice of documents on which complaints necessarily rely, *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001), publicly available financial documents such as SEC filings, *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008), and publicly available articles or other news releases of which the market was aware, *Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 n.18 (9th Cir. 1999). The Court may not assume the truth of an incorporated document “if such assumptions only serve to dispute facts in a well-pleaded complaint.” *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1003 (9th Cir. 2018).

Defendants seek judicial notice of 11 exhibits. ECF 94 at 2. Defendants contend that eight of the exhibits – Exhibits 2-3 and 6-11 – are “extensively referenced in the SAC or otherwise form the basis of Plaintiffs’ claims” and thus are incorporated by reference in the SAC. *Id.* at 3. These exhibits include press releases, SEC filings, conference call and investor presentation transcripts, and documents submitted to the FDA. *Id.* Plaintiffs agree that the 11 exhibits are incorporated by reference, but argue the Court may not assume the truth of disputed facts within the documents. ECF 100 at 10. The Court agrees with the parties, and takes judicial notice of these exhibits, and does not assume the truth of disputed facts in those exhibits. *See Khoja*, 899 F.3d at 1003.

Defendants also seek judicial notice of Exhibit 5, a publicly available FDA guidance document. Because the document is accessible on the FDA’s website as of the date of this order, *see* <https://www.fda.gov/media/109615/download>, the document’s “accuracy cannot reasonably be questioned,” making it subject to judicial notice. Fed. R. Evid. 201(b). Thus, the Court judicially notices Exhibit 5. *Immanuel Lake v. Zogenix, Inc.*, No. 19-CV01975-RS, 2020 WL 3820424, at \*5 (N.D. Cal. Jan. 27, 2020) (“[C]ourts routinely take judicial notice of [ ] FDA guidance documents, many of which also appear on the FDA’s public website.”) (citation omitted).

Finally, Plaintiffs object to Defendants’ request that the Court take judicial notice of Exhibits 1 (Review of Post-Inspection Responses) and 4 (Revance’s Form 8-K filed with the SEC on May 26, 2021) (formerly Exhibits 1 and 18, respectively). These exhibits are referenced in passing in the SAC, and neither exhibit forms the basis of Plaintiffs’ claims. For this reason, the Court finds that Exhibits 1 and 4 are not the proper subject of judicial notice.<sup>3</sup>

### **B. Motion to Strike**

Federal Rule of Civil Procedure 12(f) permits a court to “strike from a pleading . . . any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). Defendants move to strike the Sensabaugh Declaration, which Plaintiffs attached to the SAC, on the basis that it is an improper attachment because it is not a “written instrument” under Federal Rule of Civil Procedure 10(c). Rule 10(c) provides that “[a] copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes.” Many courts in this Circuit have concluded a “ ‘written instrument’ within the meaning of Rule 10(c) is ‘a document evidencing legal rights or duties or giving formal expression to a legal act or agreement, such as a deed, will, bond, lease, insurance policy or security agreement.’ ” *Nguyen v. Simpson Strong-Tie Co., Inc.*, No. 19-CV-07901-TSH, 2020 WL 5232563, at \*4 (N.D. Cal. Sept. 2, 2020) (citing *City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, No. 5:11-CV-04003-LHK, 2013 WL 2156358, at \*7 (N.D. Cal. May 17, 2013)); *see also Koehler v. Litehouse, Inc.*, No. CV 12-04055 SI, 2012 WL 6217635, at \*1 (N.D. Cal. Dec. 13, 2012). Further, many courts have determined that an expert affidavit is “merely a piece of evidentiary matter that does not exist independently of the complaint” and, accordingly, “does not qualify as a ‘written instrument.’ ” *Yuan v. Facebook, Inc.*, No. 5:18-CV-01725-EJD, 2021 WL 4503105, at \*2 (N.D. Cal. Sept. 30, 2021) (citing *In re Rigel Pharms.*, No. C 09-00546 JSW, 2010 WL 8816155, at \*1 n.1 (N.D. Cal. Aug. 24, 2010)).

The Court agrees that it is not appropriate to consider an expert affidavit on a motion to dismiss under Rule 12(b)(6). *See Juniper Networks, Inc.*, 2013 WL 2156358, at \*7. Moreover, “[a]ffidavits and declarations . . . are not allowed as pleading exhibits unless they form the basis of

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<sup>3</sup> The Court previously declined to judicially notice these exhibits. ECF 86 at 6.

the complaint.” *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003). Here, the Sensabaugh Declaration plainly is not the basis of Plaintiffs’ complaint. Rather, it was prepared for submission with the SAC, and indeed is only referenced once in the SAC as a secondary, “*see also*” cite in support of the assertion that FDA regulatory guidance requires a newly prepared WCB to be appropriately qualified by characterization and testing and presented in the product’s marketing application. SAC ¶ 76.

Because the Sensabaugh Declaration is improper under Rule 10(c), the Court **GRANTS** Defendants’ motion to strike it as an exhibit.<sup>4</sup>

### C. Motion to Dismiss

Defendants move to dismiss the SAC, arguing that Plaintiffs have insufficiently pleaded scienter. Scienter is the intent to deceive, manipulate, or defraud. *Tellabs*, 551 U.S. at 319. To establish scienter, the complaint must “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A). The required state of mind is “a mental state that not only covers ‘intent to deceive, manipulate, or defraud,’ but also ‘deliberate recklessness.’ ” *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705 (9th Cir. 2016) (internal citations omitted). Deliberate recklessness is “ ‘an *extreme* departure from the standards of ordinary care,’ which ‘presents a danger of misleading buyers or sellers that is either known to the defendant or is so *obvious* that the actor must have been aware of it.’ ” *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th at 701 (emphasis in original) (quoting *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020)).

The “strong inference” of scienter required by the PSLRA “must be more than merely ‘reasonable’ or ‘permissible’ – it must be cogent and compelling, thus strong in light of other explanations.” *Tellabs*, 551 U.S. at 324. “Facts showing mere recklessness or a motive to commit fraud and opportunity to do so provide some reasonable inference of intent, but are not sufficient to establish a strong inference of deliberate recklessness.” *In re VeriFone Holdings*, 704 F.3d at

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<sup>4</sup> Because it grants the Motion on this basis, the Court does not consider Defendants’ additional assertion that the Declaration should be struck because it amounts to an inadmissible legal opinion and unfounded speculation prohibited by Federal Rule of Evidence 702.

701. “A court must compare the malicious and innocent inferences cognizable from the facts pled in the complaint, and only allow the complaint to survive a motion to dismiss if the malicious inference is at least as compelling as any opposing innocent inference.” *Zucco*, 552 F.3d at 991; *see also Endologix*, 962 F.3d at 415. In evaluating whether a complaint satisfies the “strong inference” requirement, courts must consider the allegations and other relevant material “holistically,” not “scrutinized in isolation.” *In re VeriFone Holdings*, 704 F.3d at 701-02 (citing *Tellabs*, 551 U.S. at 323, 326). Because scienter is a subjective inquiry, “the ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity.” *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010).

In an effort to sufficiently plead scienter, Plaintiffs added two main categories of allegations to the SAC: those related to the Sensabaugh Declaration and those regarding the account of a confidential witness (“CW2”).<sup>5</sup> Because the Court struck the Sensabaugh Declaration, it does not consider the allegations regarding its contents. Plaintiffs’ other new allegations center on the account of a former Revance employee, CW2, who purportedly served as Deputy Chief of Staff from July to December 2021. SAC ¶ 136. Plaintiffs allege that CW2 coordinated meetings among Revance staff, including Defendants Foley, Schilke, Joshi, and other executives. SAC ¶ 136. CW2 witnessed an “unexpected crisis” unfold at the company on October 12, 2021, when the Form 483 – which the FDA had issued to Revance months earlier – was released publicly. SAC ¶ 138. From that day

until the end of CW2’s time at the company, the company seemed to be in crisis management mode, with Foley spending an increasing amount of time talking to analysts and shareholders. CW2’s understanding of these analyst and shareholder calls was to provide background on what the Form 483 revealed about the [Prescription Drug User Fee Act] inspection and the overall impact/potential delay to FDA approval that would result in the go-to-market launch

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<sup>5</sup> Plaintiffs also allege Revance is liable for the acts of Individual Defendants and other Revance employees under the doctrine of *respondeat superior* and common law principles of agency. SAC ¶ 127. The Court’s prior order, ECF 86, granted Plaintiffs leave to amend the FAC to address the identified deficiencies and instructed that no parties or claims could be added without leave of court or stipulation of Defendants. Plaintiffs’ introduction of this new theory of liability without consent of Defendants or leave of court thus falls outside the permission granted and violates Rule 15(a)(2). *See Striffling v. Twitter Inc.*, No. 22-CV-07739-JST, 2024 WL 54976, at \*1 (N.D. Cal. Jan. 4, 2024).

1 of DAXI.

2 SAC ¶ 139. Plaintiffs argue CW2's account bolsters their claims of scienter because "[t]he fact  
3 that the public release of the Form 483 was unexpected and led to an internal crisis at [Revance]  
4 supports an inference that Defendants intentionally concealed this information from the public."  
5 ECF 99 at 27.

6 While it is not a requirement that a confidential witness have personally interacted with  
7 defendants or have "direct knowledge of defendants' state of mind," *see* ECF 99 at 19 (citing  
8 *Roberts v. Zuora, Inc.*, No. 19-CV-03422-SI, 2020 WL 2042244, at \*10-11 (N.D. Cal. Apr. 28,  
9 2020); *In re Northpoint Commc'ns Grp., Inc., Sec. Litig.*, 221 F. Supp. 2d 1090, 1097-98 (N.D.  
10 Cal. 2002)), more is needed to show scienter than what Plaintiffs have alleged here. Indeed, this  
11 Court already held that allegations of executives' participation in regular meetings regarding FDA  
12 inspection was insufficient to demonstrate the executives' knowledge about issues with the BLA  
13 and the FDA approval process. ECF 86 at 23 (citing *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776,  
14 784 (9th Cir. 2008)). Even if Plaintiffs could show that Revance executives had knowledge of  
15 issues with the approval process, the Court already held such a showing was insufficient to meet  
16 the high standard of showing deliberate recklessness, which requires a showing of " 'an *extreme*  
17 departure from the standards of ordinary care.' " *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th at 701  
18 (emphasis in original). Allegations that Revance executives were in "crisis" following the public  
19 disclosure of the Form 483 does not, without more, naturally lead to the conclusion that  
20 Defendants intentionally concealed the information from the public or that there was an extreme  
21 departure from ordinary care. CW2's account thus fails to give rise to a "strong inference" of  
22 scienter that is "cogent and compelling, thus strong in light of other explanations." 15 U.S.C. §  
23 78u-4(b)(2)(A); *Tellabs*, 551 U.S. at 324.

24 In addition to arguing that these new allegations sufficiently plead scienter, Plaintiffs  
25 renew the arguments made to oppose dismissal of their FAC. These arguments were already  
26 considered by the Court, ECF 86 at 22-26, and the Court does not again analyze the arguments for  
27 which Plaintiffs have not pleaded additional factual allegations. Plaintiffs again contend they can  
28 show scienter under the "core operations doctrine," which permits the knowledge of certain facts

that are critical to a business’s “core operations” to be attributed to a company’s key officers. *Webb v. Solarcity Corp.*, 884 F.3d 844, 854 (9th Cir. 2018). However, “corporate management’s general awareness of the day-to-day workings of the company’s business does not establish scienter – at least absent some additional allegation of specific information conveyed to management and related to the fraud.” *Metzler*, 540 F.3d at 1068. The Court previously found that Plaintiffs failed to show scienter under the core operations theory. ECF 86 at 26. The Court reasoned that Plaintiffs had not “made ‘detailed and specific allegations’ supporting a strong inference that Defendants Schilke or Foley were intimately involved in the minutiae of the BLA process” such that they would necessarily have knowledge of the deficiencies of the Form 483. *Id.* at 25. Even if that knowledge could be imputed to them under the core operations doctrine, the Court found Plaintiffs failed to show that knowledge of manufacturing deficiencies meant that Defendants believed that the BLA was not ready or would not pass inspection. *Id.* at 26.

In the SAC, Plaintiffs add two allegations relating to their “core operations” argument regarding how Individual Defendants Foley and Schilke described DAXI as Revance’s top priority. *See* SAC ¶ 150 (“As Foley put it, getting the ‘BLA approved’ is ‘priority number one[.]’ ”); SAC ¶ 153 (“Schilke also described DAXI as Revance’s ‘core asset’ and ‘key asset.’ ”). These allegations are not “allegation[s] of specific information conveyed to management and related to the fraud” that go beyond a “general awareness of the day-to-day workings of the company’s business,” and are thus insufficient to establish scienter. *Metzler*, 540 F.3d at 1068.

Plaintiffs also allege in the SAC that the fact that Foley and Schilke signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX certifications”) shows they acted with fraudulent intent. SAC ¶¶ 101-02, 194. SOX certifications involve certifying that the information provided in the report submitted to the SEC is not misleading due to any omitted material facts. SAC ¶ 194. The caselaw is unambiguous that SOX certifications are “not sufficient, without more, to raise a strong inference of scienter.” *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 747-48 (9th Cir. 2008); *see also Zucco*, 552 F.3d at 1004 (finding boilerplate SOX certifications “add nothing substantial to the scienter calculus”); *Smith v. NetApp, Inc.*, No. 19-CV-04801-JST, 2021 WL 1233354, at \*9 (N.D. Cal. Feb. 1, 2021), *appeal dismissed sub nom.*

1 *Derouin v. NetApp, Inc.*, No. 21-15566, 2021 WL 4437682 (9th Cir. Aug. 2, 2021) (same). The  
2 SOX certifications alone thus cannot support a finding of scienter, and Plaintiffs make no  
3 argument otherwise.

4 Finding each of Plaintiffs' individual allegations insufficient, the Court now considers  
5 whether "the facts alleged, taken collectively, give rise to a strong inference of scienter." *In re*  
6 *VeriFone Holdings*, 704 F.3d at 701-02 (citing *Tellabs*, 551 U.S. at 323, 326). "Even if a set of  
7 allegations may create an inference of scienter greater than the sum of its parts, it must still be at  
8 least as compelling as an alternative innocent explanation." *Zucco*, 522 F.3d at 1006. The Court  
9 previously found that, viewed holistically, Plaintiffs' allegations in the FAC did not give rise to an  
10 overwhelming inference of deliberate recklessness as compelling as competing inferences. ECF  
11 86 at 27. The introduction of CW2's allegations does not result in a different conclusion. CW2's  
12 allegations that the Revance executives were in "crisis" following the public disclosure of the  
13 Form 483, even when viewed together with Plaintiffs' other allegations, do not give rise to an  
14 inference of scienter as "cogent or compelling" as the plausible alternatives. *Zucco*, 552 F.3d at  
15 1007. Rather, it is just as plausible that despite the FDA's issuance of a Form 483, Defendants  
16 believed any issues had or would be remedied and that DAXI would ultimately be approved.  
17 Indeed, the fact that DAXI was approved the following year makes this alternative all the more  
18 compelling.

19 Because the Court finds Plaintiffs have again not shown a cogent inference of scienter,  
20 Plaintiffs have failed to adequately plead a 10(b) claim. While the Court had previously found  
21 that some of the challenged statements may be actionable, none of Plaintiffs' claims can proceed  
22 absent scienter. Accordingly, the Court need not determine whether any of the claims would be  
23 actionable had Plaintiffs established scienter. Moreover, as Plaintiffs have failed to adequately  
24 allege a violation under Rule 10b-5/Section 10(b), Plaintiffs' Section 20(a) claim necessarily fails,  
25 as claims under Section 20(a) require an underlying violation of securities law. *In re Rigel*  
26 *Pharms.*, 697 F.3d at 886. As Plaintiffs have failed to sufficiently plead any claim, the Court thus  
27 dismisses Plaintiffs' SAC.

28 Having determined dismissal of Plaintiffs' SAC is proper, the Court must finally determine

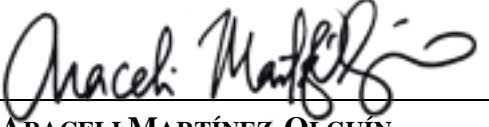
whether to grant Plaintiffs leave to amend. In their motion to dismiss, Defendants argue further amendment of the complaint would be futile. ECF 92 at 29-30. Plaintiffs did not address the futility of further amendment in their opposition to Defendants' motion. As Plaintiffs "do not identify any specific factual allegations they would add to a proposed Third Amended Complaint," the Court here finds granting leave to amend would "constitute an exercise in futility." *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1233-34 (S.D. Cal. 2001). Accordingly, dismissal without leave to amend is proper.

### CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendants' motion to strike the Sensabaugh Declaration and **GRANTS** Defendants' motion to dismiss without leave to amend.

**IT IS SO ORDERED.**

Dated: January 17, 2025

  
ARACELI MARTÍNEZ-OLGUÍN  
United States District Judge